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EXAMINER

PATTERSON, MARC A

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 07/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-12

Office Action Summary

Application No.

09/733,079

Applicant(s)

ANDERSSON ET AL.

Examiner

Marc A Patterson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

NEW REJECTIONS

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase ‘wherein following hot steam sterilization at 121 degrees Celsius the film displays no measurable yield according to DIN EN ISO 527-1 1996’ is indefinite as standard is not defined in the claim, thus the term ‘yield’ has not been defined. For purposes of examination, the claimed film will be assumed to have any yield following any test.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 – 7, 14 and 20 – 33, are rejected under 35 U.S.C. 102(b) as being anticipated by Heilmann et al (U.S. Patent No. 5,783,269).

With regard to Claims 1, 14 and 23, Heilmann et al disclose a multi – layer film comprising three layers; an inner (supporting), outer and middle layer (column 3, lines 43 – 54); each layer comprises 100% polypropylene homopolymer (column 5, lines 23 – 59); with regard to the claimed aspect of the film ‘displaying no measurable yield following steam sterilization at

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121 degrees Celsius using a water spraying process,' Heilmann discloses a sterilized film (at 121 degrees Celsius; column 4, lines 39 – 54); the claimed aspect of the film 'displaying no measurable yield following steam sterilization at 121 degrees Celsius using a water spraying process' is therefore inherent to the film disclosed by Heilmann et al, as its composition is identical to the composition of the claimed film.

With regard to Claims 2 – 4, the proportion of the thickness represented by the middle layer is 70% (column 4, lines 8 – 17).

With regard to Claims 5 – 6, the proportion of the thickness represented by the outer layer is 15% (column 4, lines 8 – 17).

With regard to Claim 7, the total thickness of the film is 130 μm (column 4, lines 8 – 17).

With regard to Claim 24, the inner layer consists of 90% polypropylene homopolymer and 10% polypropylene copolymer (column 5, lines 45 – 50).

With regard to Claim 25, the Heilmann et al teach addition of styrene – ethylene / butylene – styrene block copolymers to the layers of polypropylene (column 9, lines 31 – 37); the claimed aspect of the outer layer 'comprising styrene – ethylene / butylene – styrene block copolymers' therefore reads on Heilmann et al.

With regard to Claims 26 – 27, Heilmann et al teach that five and seven layered films are equivalent to three layered films (column 4, lines 18 – 25). The claimed aspect of the film having five or seven layers having the sequence (A-M-A-M-I) or (A-M-A-M-A-M-I) therefore reads on Heilmann et al.

With regard to Claims 28 – 31, the scope of the claims falls within the limitations of Heilmann et al as discussed above. The method of making the film (product – by – process) is

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given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from the methods of making as claimed.

With regard to Claim 32, Heilmann et al disclose a packaging comprising a multi – layer film (a bag; column 1, lines 16 – 20).

With regard to Claim 33, the packaging stores parenteral fluids (which are water – based; column 7, lines 64 – 67).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8 – 9 and 18 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269).

Heilmann et al disclose a film having an outer layer, and inner layer and a middle layer as discussed above. With regard to Claims 8 – 9 and 18 – 19, Heilmann et al fail to disclose a total film thickness of 150 – 250 μm , and a melting point of the inner layer which is less than that of the outer layer, and the melting point of the middle layer is less than that of the outer layer and greater than that of the inner layer. However, Heilmann et al disclose a film thickness of 130 μm , as discussed above, and a melting point of the inner layer which is the same as that of the outer layer, (column 7, lines 39 – 47), and a melting point of the middle layer which is less than the outer layer (column 3, lines 20 – 30). Therefore, the range of thickness and melting point of the

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middle layer and melting point of the inner layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the range of thickness and melting point of the middle layer and melting point of the inner layer, since the range of thickness and melting point of the middle layer and melting point of the inner layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

7. Claims 20 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269).

Heilmann et al disclose a film having an outer layer, and inner layer and a middle layer as discussed above. With regard to Claims 20 – 22, Heilmann et al fail to disclose a middle layer having a Vicat temperature of 40 – 65 degrees Celsius, and an outer and inner layer having Vicat temperatures less than or equal to 121 degrees Celsius. However, Heilmann et al disclose a middle layer having a Vicat temperature of 40 – 65 degrees Celsius (less than 70 degrees Celsius; column 2, lines 41 – 59), and an outer and inner layer having Vicat temperatures above 121 degrees Celsius (column 2, lines 42 – 59). Therefore, the Vicat temperatures of the inner and outer layers would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the Vicat temperatures of the inner and outer layers, since the Vicat temperatures of the inner and outer layers would be readily determined through routine

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optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

8. Claims 10 – 13 and 15 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Laurin et al (U.S. Patent No. 5,686,527).

Heilmann et al disclose a multi – layer film which is sterilizable, as discussed above. With regard to Claims 10 – 13 and 15 – 17, Heilmann et al fail to disclose a film in which the elasticity modulus of the middle layer is less than 100 MPa, and a film in which the elasticity modulus of the outer layer is greater than 400 MPa.

Laurin et al teach a modulus of elasticity for a sterilizable film, ranging from 22 – 45 kilopounds per square inch (150 – 300 MPa; column 10, lines 1 – 30) for the purpose of making a film which is easy to manufacture into useful articles (column 1, lines 45 – 54). The desirability of providing for a modulus of elasticity ranging from 22 – 45 kilopounds per square inch in Heilmann et al, which is a sterilizable film, would therefore have been obvious to one of ordinary skill in the art.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a modulus of elasticity for a sterilizable film, ranging from 22 – 45 kilopounds per square inch in Heilmann et al in order to make a film which is easy to manufacture into useful articles as taught by Laurin et al.

Laurin et al fail to disclose a modulus of elasticity of greater than 400 MPa. However, Laurin et al. disclose a modulus of elasticity of 150 – 300 MPa. Therefore, the modulus of

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elasticity would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the modulus of elasticity, since the modulus of elasticity would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Laurin et al. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

9. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Barney et al (U.S. Patent No. 6,348,568).

Heilmann et al disclose a packaging which stores parenteral fluids as discussed above. Heilmann et al fail to disclose a packaging which stores fluid lipophilic emulsions.

Barney et al teaches that parenteral fluids and lipophilic emulsions are equivalent as aqueous solutions (column 58, lines 63 – 67; column 59, lines 1 – 10) for the purpose of preparing an oily injection mixture (column 58, lines 63 – 67). The desirability of providing for fluid lipophilic emulsions in Heilmann et al, which is packaging for parenteral fluids, would therefore be obvious to one of ordinary skill in the art.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for storage of lipophilic emulsions in Heilmann et al in order to prepare an oily injection mixture as taught by Barney et al.

ANSWERS TO APPLICANT'S ARGUMENTS

10. The 35 U.S.C. 112 second paragraph rejection of Claims 1 – 34, of record on page 2 of the previous Action, have been withdrawn, except for the rejections regarding the phrase 'wherein following hot steam sterilization at 121 degrees Celsius the film displays no measurable yield according to DIN EN ISO 527-1 1996' as Applicant's arguments have been considered and have been found to be persuasive.

Applicant's arguments regarding the 35 U.S.C. 112 second paragraph rejection of the phrase 'wherein following hot steam sterilization at 121 degrees Celsius the film displays no measurable yield according to DIN EN ISO 527-1 1996,' 35 U.S.C. 102(b) rejection of Claims 1 – 7, 14 and 20 – 33 as being anticipated by Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 8 – 9 and 18 – 19 as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 20 – 22 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Laurin et al (U.S. Patent No. 5,686,527) and 35 U.S.C. 103(a) of Claim 34 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Barney et al (U.S. Patent No. 6,348,568), of record on page 2 of the previous Action, have been carefully considered but have not been found to be persuasive for the reasons set forth below.

Applicant argues, on page 8 of Paper No. 11, that the claimed element of 'no measurable yield' is neither set forth neither expressly nor inherently in Heilmann. However, as stated above, the term 'yield' is indefinite, as the test has not been defined in the claims. Furthermore, as stated above, even if the term were not indefinite, a yield which is claimed in the present invention is

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inherently taught by Heilmann, which discloses a film having the same composition as the claimed film.

Applicant also argues, on page 9, that Heilmann does teach a film that yields, as Heilmann teaches a film which is biaxially oriented. However, as stated above, the term 'yield' is indefinite; furthermore, it is unclear why a film necessarily has a particular yield by virtue of the fact that it is biaxially oriented.

Applicant also argues, on page 10, that the films disclosed by Heilmann were tested according to the claimed test, as shown in the specification, and were shown to have a measurable yield. However, it is unclear from reading the specification, where a side – by – side comparison is made between the claimed invention and Heilmann; Heilmann is mentioned at page 6 of the original specification, but not in Table 3.

Applicant also argues, on page 12, that Heilmann teaches away from routine optimization, because Heilmann teaches that 'solving a particular problem in a multi – layer coextruded film by simply making a selection from known materials is not in principle straightforwardly possible.' However, Heilmann does not teach away from the optimization of thickness of melting point, and as stated above, the range of thickness and melting point of the middle layer and melting point of the inner layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the range of thickness and melting point of the middle layer and melting point of the inner layer, since the range of thickness and melting point of the middle layer and melting point of the inner layer would be readily determined through routine optimization by one having ordinary skill in the art

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depending on the desired end result as shown by Heilmann et al. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

Applicant also argues, on page 14, that absent some teaching that the modulus of elasticity or storage of lipophilic solutions claimed by Applicant are desirable, it cannot be inferred that Applicant's invention would have been obvious to one of ordinary skill in the art. However, as stated above, Laurin et al teach a modulus of elasticity for a sterilizable film, ranging from 22 – 45 kilopounds per square inch (150 – 300 MPa; column 10, lines 1 – 30) for the purpose of making a film which is easy to manufacture into useful articles (column 1, lines 45 – 54). The desirability of providing for a modulus of elasticity ranging from 22 – 45 kilopounds per square inch in Heilmann et al, which is a sterilizable film, would therefore have been obvious to one of ordinary skill in the art.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a modulus of elasticity for a sterilizable film, ranging from 22 – 45 kilopounds per square inch in Heilmann et al in order to make a film which is easy to manufacture into useful articles as taught by Laurin et al.

Furthermore, Barney et al teaches that parenteral fluids and lipophilic emulsions are equivalent as aqueous solutions (column 58, lines 63 – 67; column 59, lines 1 – 10) for the purpose of preparing an oily injection mixture (column 58, lines 63 – 67). The desirability of providing for fluid lipophilic emulsions in Heilmann et al, which is packaging for parenteral fluids, would therefore be obvious to one of ordinary skill in the art.

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It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for storage of lipophilic emulsions in Heilmann et al in order to prepare an oily injection mixture as taught by Barney et al.

Applicant also argues, on page 16, that it is not necessary to define the terms 'DIN EN ISO 527-1 to -3' and 'yield,' as the test has been defined in the specification. However, the test in its entirety has not been defined in the specification.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Patterson, whose telephone number is (703) 305-3537. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by phone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (703) 308-4251. FAX communications should be sent to (703) 872-9310. FAXs received after 4 P.M. will not be processed until the following business day.

Marc A. Patterson, PhD.

Marc Patterson
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William P. Watkins III

**WILLIAM P. WATKINS III
PRIMARY EXAMINER**